UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,601	05/25/2006	Matthias Austen	WEICKM-0058	1728

7590 02/16/2010

Millen, White, Zelano & Branigan
Arlington Courthouse Plaza 1
2200 Clarendon Boulevard, Suite 1400
Arlington, VA 22201

EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
02/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,601	AUSTEN ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *13,14,18,24,25,42,44-63 and 67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15-17,19-23,26-41,43,64-66 and 68-72* is/are rejected.

7)☒ Claim(s) *10 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment and response of May 20, 2009, and the supplemental response dated October 21, 2009 to the Restriction Requirement dated January 9, 2009 have been entered. Claims 1, 9, 10 and 12 have been amended, and claims 71 and 72 newly added. No claims were cancelled. Accordingly, claims 1-72 are pending in the application.

Election/Restrictions

Applicants' election of Group I (claim 1-43), drawn to an *in vitro* method of using a neurturin polypeptide or a modulator/effector thereof, to stimulate and/or induce differentiation of insulin producing cells from progenitor cells is acknowledged. The election was made with traverse. Applicants' election for the species of ES cells and insulin production, applicable to the elected claims, is further acknowledged. Accordingly, claims 13, 14, 18, 24, 25, 42, 44-63 and 67 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants should note that claims directed to the intended use of the differentiated cells for treatment have not been withdrawn, as statements of intended use are generally not accorded patentable weight (MPEP 2106 II B).

Applicants' traversal is on the grounds that Johnson et al. (U.S. Patent No.: 5,739,307) does not disclose the ability of neurturin to promote differentiation of progenitor cells into insulin-secreting cells. Applicants' arguments have been fully considered, but are not found persuasive.

In response, it should be noted that the ability of neurturin polypeptide to promote differentiation of progenitor cells *in vitro* is not a special technical feature shared among all the different groups of inventions. However, as neurturin is the shared technical feature, the teachings of Johnson et al. effectively break the shared unity.

As the requirement for restriction is deemed proper, it is maintained and hereby made **FINAL**. Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the

Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

The instant claims have been examined commensurate with the scope of the elected invention, i.e. limited to a method *in vitro* differentiation of ES cells by neurturin polypeptide or a modulator/effector thereof, and not a method of administering products and cells *in vivo*.

Applicants timely responded to the restriction (election) requirement in the reply filed October 21, 2009. Claims 1-12, 15-17, 19-23, 26-41, 43, 64-66 and 68-72 are under current examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 25, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been fully considered, since several documents do not appear to be present in the application file.

Objections to the Claims & Specification

Failure to Comply with Nucleotide and /or Amino Acid Sequence Disclosures

37CFR §1.821-1.825

Claim 17 is directed to human neurturin protein published as GenBank Accession number NP 004549. The attempt to incorporate subject matter into this application by reference to a GenBank Accession no NP 004549 is ineffective because NCBI accession numbers is considered "essential subject matter" to determine the enabling embodiments. Further, in the absence of a SEQ ID NO, the sequence cannot be searched.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b) or (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier. Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

MPEP 2422.03 states [I]n those instances in which prior art sequences are only referred to in a given application by name and a publication or accession reference, they need not be included as part of the "Sequence Listing," unless an examiner considers the referred- to sequence to be "essential material," per MPEP § 608.01(p). In the instant case, GenBank accession number disclosed in the specification and claims is considered essential subject for the reasons discussed above.

The disclosure is further objected to because of the following informalities: the instant application is not in compliance with the sequence rules (see below).

This specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) as follows: the specification and claim 17 disclose GenBank Accession number NP 004549 for the neurturin protein sequence that is considered essential material and is not uniquely identified by any Sequence identification number.

Applicant must provide the following to be in compliance with the sequence rules: 1) an initial or substitute computer readable form (CRF) copy of the sequence listing; 2) an initial or substitute paper copy of the sequence listing, as well as an

amendment directing its entry into the specification; 3) a statement that the content of the paper and computer readable copies are the same and, where applicable include no new matter, as required by 37 CFR 1.821 (e), 1.821 (f), 1.821 (g), 1.825 (b) or 1.825 (d); and 4) an amendment to the specification to include an appropriate sequence identifier that properly identifies each sequence in the specification.

Claim 10 is objected to for its' recitation of "a disease going along with impaired beta-cell function", that is considered slang. It is suggested that the claim be amended to recite: "a disease associated with impaired beta-cell function"

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is unclear. The claim recites a neurturin protein or peptide which is substantially homologous to a precursor protein published as GenBank Accession Number NP 004549. The specification fails to define the degree of homology required to result in substantial homology. Thus, the metes and bounds of said homology remain undefined.

Claim 26 depends from claim 1 and recites "at least one further other pharmaceutical agent". There is no antecedent basis for "a pharmaceutical agent" in claim 1. Claims 27-29 depend from claim 26, and have thus been included in the rejection.

Claim Rejections - 35 USC § 112, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 15-17, 19-23, 26-41, 43, 64-66 and 68-72 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112 ¶1 "Written Description" Requirement, Rev. 1, 2008; at http://www.uspto.gov/web/menu/written.pdf.

The claims broadly embrace methods of inducing the differentiation of insulin producing cells from any type of progenitor cells (including adult or somatic stem cells, or cells transfected with any pancreatic gene), using modulators or effectors of neurturin protein, or variants of neurturin polypeptide, to produce differentiated pancreatic cells expressing neurturin, necessitating structure/function relationships, that are not completely described in the art or the present specification. The claims thus constitute a reach through to an enormous number of embodiments for products and substances that have yet to be established or discovered.

The specification merely discloses the induction of insulin production following differentiation of embryoid bodies comprising embryonic stem (ES) cells constitutively expressing the Pax4 gene, treated with neurturin polypeptide (Example 4; Figs. 1A and 1B). Moreover, Applicants' specification provides no examples of induced insulin production using modulators or effectors of neurturin protein, or variants of neurturin polypeptide; or any examples or descriptions of differentiation and induced insulin production by any other progenitor cells or cells transfected with pancreatic genes other than Pax-4. The disclosed structural features of the neurturin polypeptide and differentiated pax4-expressing ES cells do not constitute a substantial portion of the claimed genus, that includes modulators and effectors of neurturin yet to be discovered. As such, the Artisan of skill could not predict that Applicant possessed any additional species, except for the neurturin polypeptide and ES cells constitutively expressing the pax-4 gene. Hence, only the *in vitro* differentiation and induction of insulin production in

pax-4 expressing ES cells by treatment with neurturin protein could be demonstrated as possessed.

Thus it is clear that Applicants' description of structure and activity regarding the variants of neurturin polypeptide that include proteins and peptides substantially homologous to the amino acid sequence published as GenBank Accession Number NP 004549, or variants comprising insertion, substitution, deletion or chemical modifications of neurturin polypeptide, or the increased insulin production by any type of progenitor cell is based in large part on conjecture. The numerous variant polypeptides and progenitor cells having the requisite activities, were not known in the prior art at the time of the instant invention by Applicants, and include cells and polypeptides yet to be discovered. As the specification fails to describe the structure and activity for the genus of polypeptides and their cell substrates, the disclosed single neurturin protein and pax-4 expressing ES cells do not constitute a substantial portion of the claimed genus.

Applicant's attention is also directed to *In re Shokal*, 113 USPQ 283 (CCPA 1957), wherein it is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 CCPA (Patents) 1309, 97 F2d 623, 38 USPQ 189; *In re Wahlforss*, 28 CCPA (Patents) 867, 117 F2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

As stated in MPEP 2163 II: If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The instant specification is devoid of a description for the numerous variants of neurturin, or modulators or effectors thereof, that can induce differentiation and induction of insulin

production form any type of progenitor cell. Thus, Applicants have failed to demonstrate possession of the numerous cells and polypeptides and their reactive substrates claimed. Disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate").

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that the Artisan can reasonably conclude that the inventor(s) had possession of the claimed invention. Such possession may be demonstrated by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and/or formulae that fully set forth the claimed invention. Possession may be shown by an actual reduction to practice, showing that the invention was "ready for patenting", or by describing distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention (January 5, 2001 Fed. Reg., Vol. 66, No. 4, pp. 1099-11).

Overall, what these statements indicate is that the Applicant must provide adequate description of such core structure and function related to that core structure such that the Artisan of skill could determine the desired effect. Hence, the analysis above demonstrates that Applicants have not described the genus of neurturin variant polypeptides, or modulators or effectors of neurturin protein, that produce differentiated pancreatic cells expressing neurturin or increased insulin using any type of progenitor cell.

Therefore, the breadth of the claims as reading on numerous possible proteins or polypeptides,, including those yet to be discovered, and the differentiation of any type of progenitor cell via such products; in view of the level of knowledge or skill in the art at the time of the invention, an Artisan of skill would not recognize from the disclosure that

Applicant was in possession of the genus of molecules and cells instantly claimed. Thus it is concluded that the written description requirement is not satisfied.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a the genus of molecules or polypeptides that differentiate any type of progenitor cell into pancreatic cells that show enhanced insulin production and neurturin expression, at the time the application was filed.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 15-17, 19-23, 26-41, 43, 64-66 and 68-72 are rejected under 35 U.S.C.§112, first paragraph, because the specification, while being enabling for an *in vitro* method for stimulating and/or inducing insulin production in differentiated ES cells, comprising obtaining embryonic stem (ES) cells transformed to constitutively expressing a Pax4 gene, and differentiating said Pax-4 expressing cells in the presence of neurturin polypeptide, to produce differentiated insulin producing cells; does not reasonably provide an enablement for a method of inducing the differentiation of any type of progenitor cells from any source or progenitor cells transfected with any pancreatic gene, using variants or neurturin polypeptide, or modulators or effectors thereof, to produce insulin producing cells that further express neurturin, as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is based on issues related to the absence of an enabling disclosure for the ability to differentiate and induce insulin production via any type of progenitor cell, or to promote protection, survival or regeneration of insulin producing cells, using

neurturin or variants thereof, or modulators or effectors thereof. In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by Applicant would not have had to perform "undue experimentation" to make and/or use the invention claimed. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404:

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

MPEP § 2164.04 states: "[W]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection."

When given their broadest reasonable interpretation in view of the as filed specification, the claims broadly encompass methods of inducing the differentiation of insulin producing cells from any type of progenitor cells (including adult or somatic stem cells, or cells transfected with any pancreatic gene), using modulators or effectors of neurturin protein, or variants of neurturin polypeptide, to produce differentiated pancreatic cells expressing neurturin, and to further promote protection, survival and/or regeneration of insulin producing cells comprising contacting insulin producing cells with using neurturin protein or modulators or effector thereof.

The instant specification discloses the induction of insulin production following differentiation of embryoid bodies comprising embryonic stem (ES) cells constitutively expressing the Pax4 gene, treated with neurturin polypeptide (Example 4; Figs. 1A and 1B). However, Applicants' specification provides no examples of induced insulin production using modulators or effectors of neurturin protein, or any variants of neurturin polypeptide, that include sequences with substantial homologies, or insertions, deletions, chemical modifications or fusions with members of the GDNF family; or any examples or descriptions of differentiation and induced insulin production by any other progenitor

cells or cells transfected with any other pancreatic genes. Further, the working examples do not provide an enablement for promoting the protection, survival and/or regeneration of insulin producing cells by contacting such cells with neurturin or its modulators or effectors. Moreover, the specification provides no examples of modulators or effectors of neurturin polypeptide. The specification is further silent in providing the guidance required to demonstrate the ability of numerous variants of neurturin having substantial homology in sequence, to stimulate and/or induce differentiation of any of numerous progenitor cells, including adult somatic cells from any source. A single embodiment does not overcome the art recognized unpredictability for the various genus of polypeptides, effectors and cell types encompassed by the claims. Thus, the working examples are not commensurate in scope with the instantly claimed methods.

The state of the prior art with regard to neurturin as a neurotrophic and neural differentiation factor is effectively summarized by the references of Johnson et al. (U.S. Patent No.: 5,739,307; of record). The ability of embryonic stem cells to differentiate into insulin producing cells was additionally taught by Wobus et al. (U.S. Patent Publication No.: 2005/0054102).

The prior art at the time of filing is silent however on the ability of neurturin polypeptide to stimulate or induce the differentiation of ES cells to insulin-producing cells that produce insulin at enhanced levels, and further silent on any of the numerous possible variants, derivatives, modulators or effectors thereof having the requisite biological activity. Thus, the ability of neurturin variants or modulators or effectors to enhance the production of insulin from differentiated progenitor cells from any source remains to be established, and would further be unpredictable. The prior art is further silent on the ability of neurturin polypeptide, or its modulators or effectors to promote protection, survival and/or regeneration following contact with insulin-producing cells. No such effect has been demonstrated in either Applicants' working examples or the prior art.

It is clear from the foregoing that the instantly claimed methods are an invitation to a skilled artisan to engage in further experimentation, having unpredictable outcomes and placing an undue burden on the skilled artisan, given that the single working example

in the specification fails to qualify as a method encompassing numerous as yet undiscovered differentiation agents and cell types. Applicants should also note "case law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not to find out how to use it for themselves." *In re Gardner* 166 USPQ 138 (CCPA) 1970.

The Federal Circuit has stated that: a specification need not disclose what is well known in the art. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. *Genentech Inc. v. Novo Nordisk A/S,* 42 USPQ2d 1005 (CAFC 1997).

The guidance provided by the specification amounts to an invitation for the skilled Artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses the differentiation of constitutively Pax-4 expressing ES cells in the presence of neurturin polypeptide to produce insulin-producing cells..

The detail of the disclosure provided by Applicant, in view of the prior art, must encompass a wide knowledge, so that the Artisan of skill would be able to practice the invention as claimed by Applicant, without undue burden being imposed on such Artisan. This burden has not been met because at the time of the instant invention, the skilled artisan not have been able to predict without undue experimentation whether numerous variants, modulators and effectors of neurturin (all yet remaining to be discovered) would be able to differentiate and produce insulin-producing cells from any type of progenitor

cell, including non-transformed progenitor cells, or progenitor cells transformed with any pancreatic gene.

The instant claims have been examined in accordance with the *Wands* factors, and in view of the teachings of the prior art, the high level of unpredictability in differentiation of any type of progenitor cells to insulin-producing cells, together with the large quantity of research required to define these unpredictable variables, and the lack of guidance provided by the specification regarding the numerous possible variants of neurturin polypeptide and its as yet undiscovered modulators and effectors, it is the position of the examiner that it would require undue experimentation for one of skill in the art to practice the scope of the invention as broadly claimed. Hence, absent a strong showing by Applicant, in the way of specific guidance and direction, and/or working examples demonstrating the same, such broad inventions as claimed by Applicants are not enabled.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/
Primary Examiner, Art Unit 1633